EXHIBIT E

THE GOVERNMENT OF PUERTO RICO
COURT OF FIRST INSTANCE
SUPERIOR COURT, SAN JUAN PART

THE GOVERNMENT OF PUERTO RICO **Plaintiff,** **v.** **ELI LILLY AND COMPANY; ELI LILLY EXPORT S.A.; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; SANOFI-AVENTIS PUERTO RICO, INC.; EXPRESS SCRIPTS, INC.; CAREMARKPCS HEALTH, LLC; CAREMARK PUERTO RICO LLC; and OPTUMRX INC.** **Defendants.**	**CASE NO. SJ2023CV00319 (504)**

1. Plaintiff the Government of Puerto Rico ("Puerto Rico" or "the Government"), brings this action against Eli Lilly and Company; Eli Lilly Export S.A.; Novo Nordisk Inc.; Sanofi-Aventis U.S. LLC; and Sanofi-Aventis Puerto Rico, Inc. (collectively, "Manufacturing Defendants") and against Express Scripts, Inc.; CaremarkPCS Health, LLC; Caremark Puerto Rico LLC; and OptumRx Inc. (collectively, "PBM Defendants") pursuant to Puerto Rico's Fair Competition Act to redress all Defendants' misleading, deceptive and unlawful activity concerning their marketing and sale of insulin products to the residents of Puerto Rico, including, but not limited to artificially inflating the cost of insulin products. This practice, in effect, amounts to price gouging vulnerable Puerto Ricans whose lives depend on having access to insulin.

INTRODUCTION

2. Diabetes is a full-fledged public health epidemic in Puerto Rico. According to the International Diabetes Federation, more than 20% of Puerto Rico's adult population suffers from diabetes, totaling more than 413,000 individuals altogether.[1] In 2019, diabetes was the second leading cause of death in Puerto Rico.[2] A recent study found that nearly half of Puerto Rico's population has diabetes or pre-diabetes.[3]

3. For example, in Plan Vital—the Government's health plan—there are approximately 200,000 people with diabetes. Insulin is the second most utilized drug in the plan, and it is second only to non-insulin-based diabetes medications.

4. Approximately thirty percent of Puerto Ricans suffering from diabetes—like individuals around the world with the same condition—depend upon regular treatments of insulin to survive.[4] Insulin is one of the oldest biologic drugs (*i.e.*, drugs made from living organisms) in modern medicine. It was created nearly 100 years ago and has been widely prescribed for decades to individuals suffering from diabetes.[5]

5. Yet despite the fact that insulin has remained widely available and is critical to the care of millions of individuals throughout the nation, the Manufacturing Defendants and PBM

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[1] International Diabetes Federation, *Puerto Rico*, https://idf.org/our-network/regions-members/south-and-central-america/members/90-puerto-rico.html (last updated Apr. 4, 2022).
[2] Institute for Health Metrics and Evaluation, *Puerto Rico,* https://www.healthdata.org/puerto-rico (last visited Nov. 16, 2022).
[3] Marga Parés Arroyo, *Jóvenes puertorriqueñas relatan los retos que sobrellevan para vivir con diabetes*, El Nuevo Día (Nov. 16, 2022), https://www.elnuevodia.com/noticias/locales/notas/jovenes-puertorriquenas-relatan-los-retos-que-sobrellevan-para-vivir-con-diabetes/.
[4] Departamento de Salud, *Diabetes Puerto Rico 2020,* https://www.salud.gov.pr/CMS/DOWNLOAD/5675 (last updated Nov, 11, 2021).
[5] U.S. Food & Drug Admin., *100 Years of Insulin*, https://www.fda.gov/about-fda/fda-history-exhibits/100-years-insulin (last updated June 8, 2022).

Defendants have continued to artificially inflate their profits at the cost of patients and third-party payers.

6. Drug costs in the United States are considerably higher than drugs costs in comparable countries (*e.g.*, Australia, Canada, France, Germany, United Kingdom). For example, Humalog, which sells for over $300 in the United States, is only $30.23 in Canada.[6]

7. The PBM Defendants play a key role in skyrocketing drug prices. They deceptively represent that they work to reduce prescription drug costs. Yet, over time, they have developed a business model that does just the opposite, and in doing so, evolved business practices designed to maximize their own profit, to the detriment of consumers with diabetes.

8. Pharmacy benefit managers ("PBMs"), which operate only in the United States, are administrators hired by third-party payers (*e.g.*, government entities, insurers, employers) to design and administer prescription drug programs, including by creating drug formularies—lists of prescription drugs covered by health plans tiered according to consumers' cost-share obligations (*e.g.*, tier 1 drugs require a $5 co-payment, tier 2 drugs require a $10 co-payment, and so forth).

9. Inclusion on drug formularies is crucial to the profitability and sales of prescription drugs. If a drug is not included on a PBM's formulary, consumers must pay out-of-pocket for it—making the drug unaffordable for many consumers. Formulary and insurance coverage thus affect all levels of the health care industry. Prescription drug manufacturers recognize this fact and dedicate substantial marketing and other resources to ensure that their prescription drugs are included on PBMs' drug formularies.

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[6] Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95(1) Mayo Clinic Proc. 22 (Jan. 1, 2020), https://doi.org/10.1016/j.mayocp.2019.11.013; Ontario Drug Benefit Formulary/Comparative Drug Index, https://www.formulary.health.gov.on.ca/formulary/results.xhtml?q=Humalog&type=2 (last visited Nov. 16, 2022).

10. Prescription drug manufacturers establish the wholesale acquisition cost ("WAC") (known as the "list price" or "sticker price") for their drugs. But the list price typically bears little to no resemblance to the prices consumers and third-party payers actually pay for drugs. This complex and opaque pricing system allows middlemen—like the PBM Defendants—to siphon increasing amounts of money from the pharmaceutical supply chain while significantly increasing prices for consumers, employers, and other health care payers.

11. Prescription drug manufacturers pay rebates and other fees to PBMs to ensure their drugs will receive preferential placement on PBMs' drug formularies. Rebates are post-sale discounts that drug manufacturers pay to the PBMs, not consumers, based on the number of consumers that fill a prescription for the manufacturers' drug. Again, these rebates are not passed on to individual consumers.

12. The three PBM Defendants collectively manage 80% of drug benefits for more than 220 million Americans. As such, the prospect of placement on these three PBMs' drug formularies is a significant bargaining chip when negotiating rebates with prescription drug manufacturers.

13. Around 2012, the PBM Defendants began increasingly exerting their leverage against prescription drug manufacturers to demand higher rebates and other payments—of which PBMs typically retain a percentage. One tactic the PBM Defendants use to maximize drug rebates is to exclude one or more drugs used to treat the same condition to intensify competition among manufacturers.

14. In response to this rebating strategy, prescription drug manufacturers began to increase the WAC price, or list price, for their drugs as a way to maintain their profit margins. For example, if Drug Manufacturer A's list price for a given drug was $100, and a PBM wanted a $20

rebate, Drug Manufacturer A would give the PBM the $20 rebate and increase the list price to $120, to keep its profit margin.

15. Since 2014, there has been a fundamental shift in payments from prescription drug manufacturers to PBMs. Manufacturer payments to PBMs and other intermediaries have risen by over 16% per annum and now constitute 40% or more of branded prescription drug costs.[7]

16. In 2021, the U.S. Senate Finance Committee released the results of their bipartisan investigation into the skyrocketing price of insulin. One of their key findings was that rebates for insulin products have increased "exponentially" since 2013.[8] For example, in 2013, the manufacturer Sanofi offered rebates between 2% and 4% for insulin products to gain preferred placement on CVS Caremark's formulary. By contrast, in 2018, Sanofi's rebates for insulin products were as high as 56% for preferred formulary placement.[9]

17. Not surprisingly, the list price of insulin rose along with the rebates. In 1996, when Eli Lilly launched Humalog, the price for a 1-month supply of insulin was $21.[10] That same vial of insulin was $35 in 2001 and around $275 in 2019—***a 1200% increase from the original price***.[11]

18. This artificial price increase is almost entirely due to Defendants' rebate practices. Neither manufacturing costs nor distribution costs justify such a massive increase. A 2018 study

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[7] Emery P. Weinstein and Kevin Schulman, *Exploring Payments in the U.S. Pharmaceutical Market 2011-2019: Update on Pharmacy Benefit Manager Impact*, 227 Am. Heart J. 107-110 (2020), https://doi.org/10.1016/j.ahj.2020.06.017.
[8] United States Senate Finance Committee, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, at 7 (Jan. 14, 2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf (hereinafter referred to as "Senate Insulin Report").
[9] *Id*. at 82.
[10] Danielle K. Roberts, *The Deadly Costs of Insulin*, AJMC (June 10, 2019), https://www.ajmc.com/view/the-deadly-costs-of-insulin.
[11] *Id*.

found that, depending on the type of insulin, one vial of insulin costs around $2 to $6 to produce. Further, it found that insulin manufacturers could profit by selling their insulin products at $72 per patient per year or less for human insulin and $133 per patient per year or less for analog insulins.[12]

19. This pricing scheme benefits Manufacturing Defendants because it allows them to essentially buy market share and thereby guarantee the success of their insulin products. It also benefits PBM Defendants because it allows them to profit from growing rebates and other fees tied to the WAC price. But the scheme harms the most vulnerable: diabetic consumers.

20. Many consumers' out-of-pocket payments for insulin are tied to the WAC price—so that consumers' out-of-pocket payments increase when the WAC price increases. Also, the PBM Defendants' tactics increase the risk of non-medical switching—altering a patient's drug therapy for reasons other than a drug's efficacy, side effects, or clinical outcome, which happens when PBMs exclude drugs and switch patients to competing drugs for which the PBMs were able to extract higher rebates. Further, it overlooks the fact that even though drugs may treat the same condition, some drugs produce better outcomes for certain patients.

21. This action seeks injunctive relief, restitution, disgorgement, civil penalties, and damages, to address the harm caused by the Defendants.

PARTIES

Plaintiff Government of Puerto Rico

22. Plaintiff, Government of Puerto Rico, by and through the Secretary of Justice of Puerto Rico, Domingo Emanuelli Hernández, brings this action to protect the interests of Puerto Rico and its residents. The Secretary of Justice brings this action pursuant to his statutory authority

[12] Dzintars Gotham et al., *Production costs and potential prices for biosimilars of human insulin and insulin analogues*, BMJ Glob Health (Sept. 25, 2018), https://gh.bmj.com/content/3/5/e000850.info.

under 10 L.P.R.A. § 269 to enforce the Puerto Rico laws prohibiting unfair methods of competition and unfair or deceptive acts or practices in trade or commerce.

23. The Government is not seeking relief relating to any federal program (*e.g.*, Medicaid, Medicare) or any contract related to a federal program. Moreover, the Government's claims do not arise out of a written contract, but rather are based on the larger unfair and deceptive scheme that violates the Fair Competition Act and increased prices and reduced access to insulin products for Puerto Rico consumers.

Defendants Eli Lilly and Company and Eli Lilly Export S.A.

24. Defendant Eli Lilly and Company is an Indiana corporation with its principal place of business in Indiana. Eli Lilly manufactures, promotes, and sells several insulin medications, including Humulin N, Humulin R, Humalog, and Basaglar, all of which are dispensed in Puerto Rico to Puerto Rico residents.

25. Eli Lilly and Company's affiliate in Puerto Rico is Eli Lilly Export S.A. ("Eli Lilly Export") (hereinafter Eli Lilly and Company and Eli Lilly Export will be referred to collectively as "Eli Lilly"). Eli Lilly Export is a Puerto Rico corporation that has spent at least hundreds of thousands of dollars from 2015 to 2021 to market Eli Lilly and Company's products—including insulin products—to physicians in Puerto Rico.[13]

26. Eli Lilly employs sales representatives in Puerto Rico to promote and sell insulin products. Eli Lilly also directs advertising and informational materials to Puerto Rico physicians, payers, and diabetics for the specific purpose of selling more insulin products in Puerto Rico.

[13] Open Payments, *Eli Lilly Export S.A. Puerto Rico Branch*, https://openpaymentsdata.cms.gov/company/100000000331 (last visited Nov. 27, 2022).

27. At all times relevant to this complaint, Eli Lilly caused its artificially inflated list prices to be published throughout the United States, including Puerto Rico, with the express knowledge that Puerto Rico residents with diabetes's payments and reimbursements would be based on those prices. Eli Lilly promoted its insulin products in Puerto Rico, including through its in-person sales representatives.

Defendant Novo Nordisk Inc.

28. Novo Nordisk Inc. ("Novo Nordisk") is a Delaware corporation with its principal place of business in New Jersey. Novo Nordisk is registered to do business in Puerto Rico. Novo Nordisk manufactures, promotes, and sells several insulin medications, including Novolin R, Novolin N, Novolog, Levemir, and Tresiba, all of which are dispensed in Puerto Rico to Puerto Rico residents.

29. Novo Nordisk employs sales representatives in Puerto Rico to promote and sell insulin products. Upon information and belief, Novo Nordisk also directs advertising and informational materials to Puerto Rico physicians, payers, and diabetics for the specific purpose of selling more insulin products in Puerto Rico.

30. At all times relevant to this complaint, Novo Nordisk caused its artificially inflated list prices to be published throughout the United States, including Puerto Rico, with the express knowledge that Puerto Rico residents with diabetes's payments and reimbursements would be based on those prices. Novo Nordisk promoted its insulin products in Puerto Rico, including through its in-person sales representatives.

Defendants Sanofi-Aventis U.S. LLC and Sanofi-Aventis Puerto Rico, Inc.

31. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company with its principal place of business in New Jersey. Sanofi manufactures, promotes, and sells several

insulin products, including Lantus, Toujeo, Soliqua, and Apidra, all of which are dispensed in Puerto Rico to Puerto Rico residents.

32. Sanofi U.S.'s affiliate in Puerto Rico is Sanofi-Aventis Puerto Rico Inc. Sanofi-Aventis Puerto Rico Inc. is a Puerto Rico corporation (hereinafter Sanofi-Aventis U.S. LLC and Sanofi-Aventis Puerto Rico Inc. will be collectively referred to as "Sanofi").

33. Sanofi employs sales representatives in Puerto Rico to promote and sell Lantus, Toujeo, Soliqua, and Apidra. Upon information and belief, Sanofi also directs advertising and informational materials to Puerto Rico physicians, payers, and diabetics for the specific purpose of selling more insulin products in Puerto Rico.

34. At all times relevant to this complaint, Sanofi caused its artificially inflated list prices to be published throughout the United States, including Puerto Rico, with the express knowledge that Puerto Rico residents with diabetes's payments and reimbursements would be based on those prices. Sanofi promoted its insulin products in Puerto Rico, including through its in-person sales representatives.

35. Collectively, Eli Lilly, Novo Nordisk, and Sanofi are known as the "Manufacturer Defendants."

Defendants CaremarkPCS Health, LLC and Caremark Puerto Rico LLC

36. Defendant CaremarkPCS Health, LLC (operating as CVS Caremark) is a Delaware limited liability company that maintains its principal place of business in Rhode Island. At all times relevant to this complaint, CVS Caremark provided pharmacy benefit management services in Puerto Rico.

37. CaremarkPCS Health, LLC's affiliate in Puerto Rico is Caremark Puerto Rico LLC (hereinafter CaremarkPCS Health, LLC and Caremark Puerto Rico LLC will be collectively

referred to as "CVS Caremark"). Caremark Puerto Rico LLC is a Puerto Rico limited liability company.

38. At all relevant times, CVS Caremark had agreements with the Manufacturer Defendants related to payments for placement on CVS Caremark's standard formularies.

39. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 33% of the national market.[14]

Defendant Express Scripts, Inc.

40. Defendant Express Scripts, Inc. ("Express Scripts") is a Delaware corporation that maintains its principal place of business in Missouri and is registered to do business in Puerto Rico. At all times relevant to this complaint, Express Scripts provided pharmacy benefit management services in Puerto Rico.

41. At all relevant times, Express Scripts had agreements with the Manufacturer Defendants related to payments for placement on Express Scripts' standard formularies.

42. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Complaint, Express Scripts controlled 30% of the PBM market in the United States.[15]

Defendant OptumRx, Inc.

43. Defendant OptumRx, Inc. ("OptumRx) is a California corporation that maintains its principal place of business in California and is registered to do business in Puerto Rico. At all times relevant to this complaint, OptumRx provided pharmacy benefit management services in Puerto Rico.

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[14] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger*, Drug Channels (Apr. 5, 2022), https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html.
[15] *Id*.

44. At all relevant times, OptumRx had agreements with the Manufacturer Defendants related to payments for placement on OptumRx's standard formularies.

45. During the relevant period of this Complaint, OptumRx controlled 21% of the PBM market in the United States.[16]

46. Collectively, CVS Caremark, Express Scripts, and OptumRx are referred to as "PBM Defendants."

47. Collectively, the "PBM Defendants" and the "Manufacturer Defendants" are referred to as "Defendants."

JURISDICTION AND VENUE

48. This Court has jurisdiction over this case pursuant to 10 L.P.R.A. § 269, which confers jurisdiction on this Court to award the relief sought by the Government, including injunctions and such other further relief as may be appropriate.

49. This Court has personal jurisdiction over Defendants in this matter pursuant to Puerto Rico Rules of Civil Procedure 3.1(a), 32 L.P.R.A. App. V, R. 3.1(a), as well as the due process clause of the United States Constitution, by transacting business in Puerto Rico and participating in tortious acts within Puerto Rico.

BACKGROUND

I. The Importance of Insulin Therapy in Diabetes

50. Diabetes is a condition affecting approximately 37 million people nationwide (roughly one in 10) and 430,000 people in Puerto Rico (roughly 2 in 13).[17] Diabetes is manageable

[16] *Id.*

[17] U.S. Centers for Disease Control and Prevention, *The Facts, Stats, and Impacts of Diabetes*, https://www.cdc.gov/diabetes/library/spotlights/diabetes-facts-stats.html (last updated Jan. 24, 2022); International Diabetes Federation, *Puerto Rico*, https://idf.org/our-network/regions-members/south-and-central-america/members/90-puerto-rico.html (last updated Apr. 4, 2022).

with injections of insulin, but missing insulin doses can produce excessive blood sugar leading to a toxic condition called ketoacidosis.[18]

51. Even though insulin was first extracted nearly 100 years ago, three companies, Eli Lilly, Novo Nordisk, and Sanofi, manufacture virtually all of the insulin in the United States.[19]

52. There are different types of insulin. The first insulins were derived from animals.[20] In 1982, Eli Lilly developed the first biosynthetic human insulin known as Humulin.[21] In 1996, Eli Lilly developed an analog insulin called Humalog. Analog insulins, which have largely replaced human insulins, are similar to biosynthetic human insulin but are modified to mimic the body's natural pattern of insulin release and have more predictable duration of action.[22]

53. Insulins are also categorized by differences in onset—typically, fast-acting insulins, intermediate-acting insulins, and long-acting insulins.[23] Diabetics take a combination of insulins to control their blood sugar based on numerous factors, including activity level, diet, and age.

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[18] U.S. Centers for Disease Control and Prevention, *Diabetic Ketoacidosis*, https://www.cdc.gov/diabetes/basics/diabetic-ketoacidosis.html (last updated Mar. 25, 2021).
[19] William T. Cefalu et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 Diabetes Care 1299 (2018), https://diabetesjournals.org/care/article/41/6/1299/36487/Insulin-Access-and-Affordability-Working-Group.
[20] American Diabetes Association, *The History of a Wonderful Thing We Call Insulin* (July 1, 2019), https://diabetes.org/blog/history-wonderful-thing-we-call-insulin.
[21] *Id*.
[22] University of California, San Francisco, *Diabetes Education Online-Insulin Analogs*, https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/insulin-analogs/ (last visited Nov. 16, 2022).
[23] University of California, San Francisco, *Diabetes Education Online-Types of Insulin*, https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/ (last visited Nov. 16, 2022).

II. Insulin Prices Have Skyrocketed Over the Last Couple of Decades

54. Insulin is a prime example of skyrocketing drug costs. From 2014 to 2020, drug prices increased by 33%, outpacing inflation and price increases for any other medical commodity or service.[24]

55. In 1996, Eli Lilly's Humalog was priced at $21.[25] That same vial of insulin increased to $35 in 2001 and to $275 in 2019—***a 1200% increase from the original price***.[26]

56. The staggering price increases in the United States—the only country that uses PBMs—are not matched globally. In the Province of Ontario, Canada, Eli Lilly marketed Humalog for $30.23 in 2021.[27]

57. For an insulin-dependent diabetic person with commercial insurance, the annual cost of insulin nearly doubled from approximately $3,200 in 2012 to $5,900 in 2016.[28]

58. The rising cost of insulin has dire consequences. A study from New Haven, Connecticut revealed that one in four people with diabetes at an urban medical center reported cost-related insulin underuse. Diabetics who reported financial challenges associated with insulin

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[24] Tori Marsh, *Prices for Prescription Drugs Rise Faster Than Prices for Any Other Medical Good or Service*, GoodRx Health (Sept. 17, 2020), https://www.goodrx.com/healthcare-access/drug-cost-and-savings/prescription-drugs-rise-faster-than-medical-goods-or-services; Stephen W. Schondelmeyer and Leigh Purvis, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2020*, AARP Public Policy Institute at 1 (June 2021), https://www.aarp.org/content/dam/aarp/ppi/2021/06/trends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans.10.26419-2Fppi.00143.001.pdf.

[25] Roberts, *supra* note 10.

[26] *Id*.

[27] Ontario Drug Benefit Formulary/Comparative Drug Index, https://www.formulary.health.gov.on.ca/formulary/results.xhtml?q=Humalog&type=2 (last visited Jan. 30, 2022).

[28] Jean Fuglesten Biniek and William Johnson, *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*, Health Care Cost Institute (Jan. 21, 2019), https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices.

prices were more likely to have poor glycemic control (clinical management of their diabetes), which leads to negative health outcomes, such as blindness, amputations, and even death.[29]

III. The PBM Defendants Provide Services to Consumers

59. The PBM Defendants provide services to consumers by administering prescription drug benefits. As CVS Caremark explains to consumers through its welcome kit: "We manage your prescription drug benefits just like your health insurance company manages your medical benefits."[30]

60. The PBM Defendants provide identification cards to consumers with their company logos to present to pharmacies for the purpose of determining consumers' prescription drug coverage.

61. All of the PBM Defendant families have consumer-facing websites representing that they "serve" consumers and that consumers are their "members."[31]

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[29] Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, 179(1) JAMA Intern Med. 112, 112-114 (Jan. 2019), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2717499; Mary Caffrey, *Gathering Evidence on Insulin Rationing: Answers and Future Questions*, AJMC (Sept. 26, 2019), https://www.ajmc.com/view/gathering-evidence-on-insulin-rationing-answers-and-future-questions.

[30] CVS Caremark, *Welcome Kit*, https://benefits.vmware.com/wp-content/uploads/2018/10/CVS-Caremark-Sample-Welcome-Kit_ID-Card.pdf (last visited Nov. 16, 2022).

[31] CVS Caremark, https://www.caremark.com/welcome-center.html#tab_link_tabs_2 (last visited Nov. 16, 2022); CVS Caremark, https://www.caremark.com/about-us.html (last visited Nov. 16, 2022).

Express Scripts, Inc., https://www.express-scripts.com/corporate/about (last visited Nov. 16, 2022); Express Scripts, Inc., *Frequently Asked Questions*, https://www.express-scripts.com/frequently-asked-questions/about (last visited Nov. 16, 2022); Express Scripts, Inc., *Who We Help Overview*, https://www.express-scripts.com/corporate/who-we-help/members (last visited Nov. 16, 2022).

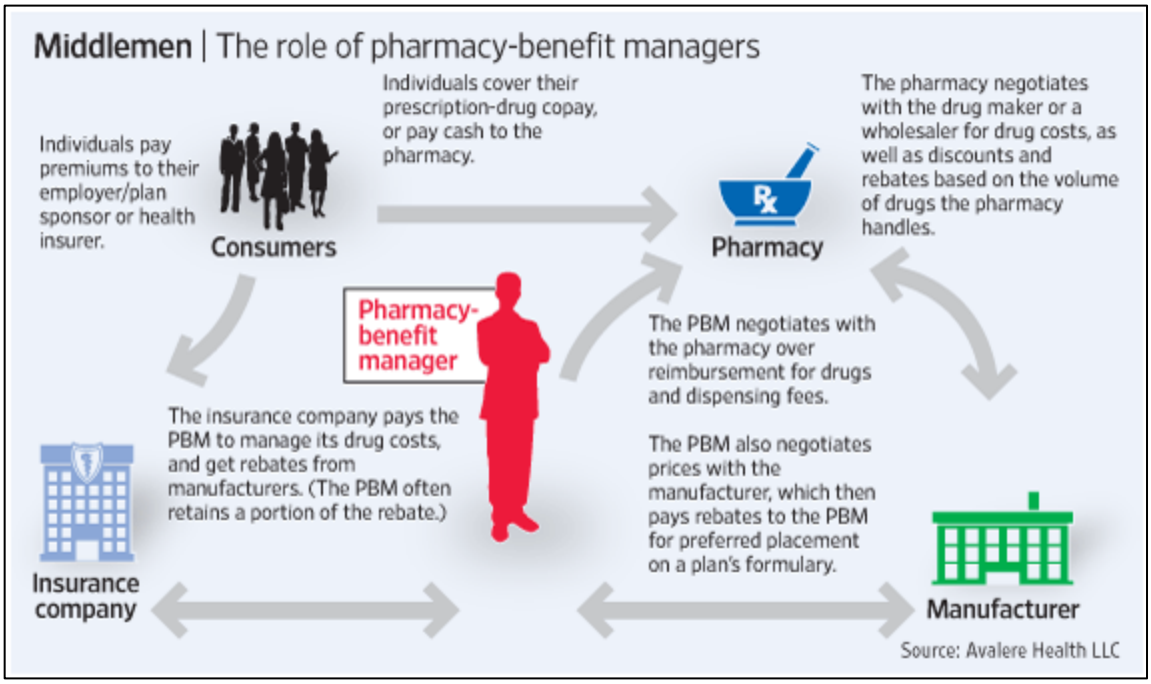
OptumRx Inc., optumrx.com (last visited Nov. 16, 2022); OptumRx Inc., *OptumRx Welcome Video*, https://optumrx.video.uhc.com/media/OptumRx+Welcome+Video/0_ug0m5mm2 (last visited Nov. 16, 2022).

62. The PBM Defendants further represent on their websites that giving consumers access to necessary prescription drugs at an affordable price is a top priority.[32]

IV. The PBM Defendants Are Middlemen in a Complex Drug Pricing System

63. PBMs—like the PBM Defendants—act as intermediaries between their third-party payers, such as government entities, insurers, and employers, and other entities in the drug distribution chain, such as prescription drug manufacturers and pharmacies (as shown in the chart below).[33] PBMs are involved in, and benefit from, almost every link in the chain.

Figure 1: The Role of Pharmacy Benefit Managers



64. Consumers pay premiums to their employers or insurance companies (third-party payers) for health insurance. Third-party payers then pay PBMs to administer prescription drug benefits for consumers. PBMs in turn negotiate and contract with pharmacies to determine the

[32] *Id.*
[33] Dan Fleshler, *Opening Up the Black Box on PBMs (Pharmacy Benefit Managers)*, healthline (Sept. 21, 2018), https://www.healthline.com/diabetesmine/PBM-primer.

amount PBMs will pay pharmacies for prescription drugs (minus any cost-share amounts that consumers pay directly to pharmacies).

Consumer Costs Are Typically Linked to the WAC Price

65. Consumers' out-of-pocket costs for drugs are determined by whether they have insurance and the terms of their coverage. Consumer payments range from high to low from 1) the cash price (either because consumers are uninsured or have a high-deductible plan), to 2) a cost-share payment based on a percentage of drug costs, to 3) what is typically the least expensive option, a flat copayment.

66. Consumers without insurance pay the "usual and customary" price (*i.e.*, the "cash price")—typically greater than the WAC price, which federal law defines as the manufacturer's list price to wholesalers and direct purchasers (not including rebates or other discounts). *See* 42 USC § 1395w-3a(c)(6)(B). For example, the WAC price for Lantus (Sanofi's top-selling insulin) is $283.56 per vial and the average retail price for Lantus is $343 per vial.[34]

67. In addition, an increasing number of consumers have high-deductible plans, which require consumers to pay the cash price for drugs until they meet their deductible—averaging nearly $2,200 a year.[35]

[34] Sanofi-Aventis U.S. LLC, *Lantus Pricing Sheet*, https://www.lantus.com/-/media/EMS/Conditions/Diabetes/Brands/lantus-final/Header/Lantus-Pricing.pdf (last visited Nov. 16, 2022); Benita Lee, *How Much Does Insulin cost? Here's How 28 Brands and Generics Compare*, GoodRx Health (Jan. 26, 2022), https://www.goodrx.com/healthcare-access/research/how-much-does-insulin-cost-compare-brands.

[35] Gary Claxton et al., *Employer Health Benefits 2020 Annual Survey, Kaiser Family Foundation*, at 137 (Oct. 8, 2020), https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf.

68. About 30-50% of insured consumers pay a coinsurance amount, which is a percentage of the WAC price (not including rebates).[36]

69. Other insured consumers pay a flat copayment amount, such as $5 for generic drugs and $10 for preferred brand-name drugs. The copayment is not directly tied to the WAC price; however, the overall cost of drugs factors into a plan's decision when determining health insurance premiums and consumer copayment amounts.

PBMs Obtain Payments from Manufacturers Classified as Rebates, Administrative Fees, and Price Protections

70. In addition to relationships with third-party payers and pharmacies, PBMs negotiate and contract for various payments from prescription drug manufacturers. The bulk of these payments are for rebates.

71. Manufacturers typically offer rebates only for branded drugs, not generics. Typically, branded drugs account for a small percentage of drug utilization but the vast majority of drug spending. For example, for Plan Vital, the branded drug utilization rate is less than 10%, but branded drugs account for approximately 80% of drug spending.

72. Prescription drug rebates are reductions from the WAC price redeemed from manufacturers after the transaction. Yet, unlike traditional rebates, manufacturers pay prescription drug rebates to PBMs, not to insured (or uninsured) consumers who paid the WAC price.

73. In a quid pro quo agreement, prescription drug manufacturers pay rebates and other fees to PBMs for the purpose of securing placement on the PBMs' drug formularies.

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[36] Lisa L. Gill, *The Shocking Rise of Prescription Drug Prices: Here's why prices keep going up, plus how to combat the sticker shock—and still protect your health*, Consumer Reports (Nov. 26, 2019), https://www.consumerreports.org/drug-prices/the-shocking-rise-of-prescription-drug-prices/.

74. A drug formulary is a list of generic and brand name prescription drugs covered by health plans. Formularies are usually divided into three to five tiers that determine consumers' cost-share amounts (*e.g.*, the co-payment or co-insurance) consumers must pay toward the cost of a prescription. The lower tiers have lower cost-share amounts than the higher tiers. For example, a typical three-tier formulary may be designed as follows:

- Tier 1 contains generic drugs with the lowest cost-share amount for consumers.
- Tier 2 contains preferred brand-name drugs with a cost-share amount that is higher than tier 1 but lower than tier 3.
- Tier 3 contains non-preferred brand-name drugs with the highest payment by consumers.

75. Generally, prescription drug manufacturers pay higher rebates for preferred formulary placement (*i.e.*, tier 2 status instead of tier 3 status). This is because prescribers are more likely to write prescriptions and consumers to fill prescriptions for drugs with lower cost-share amounts.

76. The rebates PBMs negotiate are highly confidential and, for the most part, the exact terms of the agreements between PBMs and prescription drug manufacturers are unknown to others in the supply chain—creating a pricing black box.

77. Drug rebates are usually based on the WAC price. For example, a manufacturer may offer the PBM a rebate of 40% of the WAC price for a particular drug.

78. In addition to prescription drug rebates, manufacturers pay various fees to PBMs, including administrative fees and fees for price protection.

79. In another quid pro quo agreement, manufacturers pay PBMs administrative fees for administering rebates, which are separate from any administrative fees PBMs may charge third-

party payers. Like rebates, administrative fees are tied to the WAC price and paid according to PBMs' confidential contracts with manufacturers. Administrative fees typically range from 3% to 5% of the WAC price.[37]

80. Price protection is another way that PBMs extract payments. PBMs present price protection as a means to reduce costs, but the Senate Finance Committee's investigation of insulin pricing revealed price protection does very little to keep costs down. Price protection establishes a cap on the amount by which prescription drug manufacturers can increase the WAC price for a particular drug (ranging from 0% to 12%).[38] Any price increase by manufacturers above the established cap triggers additional rebate payments to PBMs known as "price protection." For example, if there is a 5% cap on the WAC price, and the manufacturer increases the WAC price by more than 5%, the manufacturer must pay additional rebates (*e.g.*, 50% of the WAC price instead of 45% of the WAC price) of which PBMs typically retain a portion. Price protection does not provide any discount to consumers at the point of sale.

81. Under a traditional PBM pricing model, PBMs retain a portion of the payments they receive from prescription drug manufacturers and return the remainder to third-party payers.

FACTUAL ALLEGATIONS

I. The PBM Defendants Deceptively Represent That They Lower Drug Prices

82. The PBM Defendants have made numerous deceptive representations about their role in the market—mainly that they serve to lower prices.

83. CVS Caremark represents "[w]e reduce prescription drug costs" and that "[a]s the health care system becomes increasingly complex and drugs become more expensive, our work

[37] Senate Insulin Report, *supra* note 8 at 82.
[38] *Id*. at 84.

has never been more important."[39] CVS Caremark further claims "[w]e work hard to keep prices down because we know that people who take their medications as prescribed have better outcomes and lower health care costs."[40] CVS Caremark also represents:

- "MYTH: Rebates negotiated by PBMs are driving up the prices of prescription drugs for consumers and plan sponsorship. FACT: Pharmaceutical manufacturers set the list price for a given drug. PBMs then negotiate with manufacturers to secure the drug at a lower cost for their plan sponsors and their members."[41]

- "MYTH: PBMs increase cost-sharing burdens for beneficiaries. FACT: Plan designs are determined by clients – employers and health plans – who decide how they subsidize their members' coverage."[42]

- "MYTH: PBMs lower drug costs by restricting patient access to needed medication. FACT: PBMs help ensure that beneficiaries have access to the prescriptions they need to stay healthy, at a price they can afford."[43]

- "As a PBM and an Employer, We Know Rebates and Innovation Lower Drug Costs"[44]

- Making sure you have access to affordable medication and convenient options for filling is our priority"[45]

84. In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure "that the cost of a drug is aligned with the value it delivers in terms of patient

[39] CVS Health, *Prescription Drug Coverage*, https://www.cvshealth.com/our-services/prescription-drug-coverage (last visited Nov. 16, 2022).
[40] CVS Health, *Prescription Drug Savings*, https://www.cvshealth.com/our-services/prescription-drug-coverage/prescription-drug-savings (last visited Nov. 16, 2022).
[41] CVS Health, *Myths vs. Fact Pharmacy Benefit Management*, at 2 (Jan. 2021), https://www.cvshealth.com/sites/default/files/cvs-health-myth-vs-fact-pbm-2021-01.pdf.
[42] *Id*. at 3.
[43] *Id*. at 4.
[44] @CVSHealth, Twitter (Oct. 31, 2018, 11:11 AM), https://twitter.com/CVSHealth/status/1057651382155653121.
[45] CVS Caremark, caremark.com (last visited Jan. 25, 2022).

outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Saving Patients Money initiative."[46]

85. On August 31, 2016, an Express Scripts news release quoted Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts as stating: "Diabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payers . . . [Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease." The statement further represented that Express Scripts "broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs."[47]

86. Express Scripts claims it "works with plan sponsors to provide a benefit that delivers the best clinical outcome and the lowest possible cost."[48] It also represents:

- "PBMs provide better care and lower cost with every prescription, every time."[49]
- "Rebates do not raise drug prices, drug makers raise drug prices, and they alone can lower them. Consider the cost of Humalog® (insulin lispro): over the past seven years, the list price for this medication has increased dramatically, yet the net cost has remained relativity constant. Without PBMs, and specifically without Express Scripts, plan sponsors would have paid exponentially more for their prescription drugs."[50]

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[46] CVS Caremark, Drug Trend Report 2017, at 3 (2017), https://payorsolutions.cvshealth.com/sites/default/files/cvs-health-payor-solutions-2017-drug-trend-report-feature-april-2017.pdf.
[47] Express Scripts, Inc., *Express Scripts Launches Diabetes Care Value Program, Guaranteeing More Affordable, Higher-Quality Diabetes Care*, Cison (Aug. 31, 2016), https://www.prnewswire.com/news-releases/express-scripts-launches-diabetes-care-value-program-guaranteeing-more-affordable-higher-quality-diabetes-care-300320485.html.
[48] Paul Reyes, *What's a Pharmacy Benefit Manager*, Express Scripts (Aug. 1, 2019), https://www.express-scripts.com/corporate/articles/whats-pharmacy-benefit-manager.
[49] *Id*.
[50] Express Scripts, Inc., *The Rebate Debate* (June 29, 2017), https://www.express-scripts.com/corporate/articles/rebate-debate.

- "We . . . negotiate with drug manufacturers so no one pays more than they need to."[51]"FACT: Public disclosure of negotiated rebates will not lower prescription drug costs. #PBMs Express Scripts negotiates with drug manufacturers to increase competition and lower costs for patients."[52]

87. Further, Express Scripts' publicly available code of conduct states, "[a]t Express Scripts we're dedicated to keeping our promises to patients and clients[.]"[53]

88. OptumRx claims "Rebates are a longstanding tool used by PBMs to negotiate with drug manufacturers to achieve lower prescription drugs costs for clients."[54] It also represents:

- "PBMs develop pharmacy networks, negotiate with drug companies for the best medication prices, process pharmacy claims, and may operate a home delivery pharmacy."[55]

- "Learn how we make the consumer experience a top priority to create better outcomes, lower costs, and improve the overall healthcare system."[56]

- "Helping millions of people get medication safely, conveniently and at the best price."[57]

- "We strive to contain medication costs and our clinical programs are designed to provide better care and outcomes."[58]

89. OptumRx's Chief Executive Officer testified before Congress that: "OptumRx's pharmacy care services business is achieving better health outcomes for

[51] Reyes, *supra* note 48.
[52] @ExpressScripts, Twitter (Apr. 9, 2019, 3:10 PM), https://twitter.com/ExpressScripts/status/1115693403285741568.
[53] Express Scripts Inc., *Code of Conduct*, at 4 (Dec. 2015), https://www.express-scripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf.
[54] OptumRx, *Regulatory developments affecting pharmacy*, (Feb. 2022), https://www.optum.com/business/resources/library/regulatory-updates-q1-2022.html.
[55] Kevira Voegele, *Who is OptumRx?*, OptumRx (Sept. 4, 2018), https://optumrx.video.uhc.com/media/Who+is+OptumRxF/0_8lrxn39l.
[56] @OptumRx, Twitter (Sept. 8, 2020), https://twitter.com/OptumRx/status/1303226564751036416.
[57] Kevira Voegele, *What is a formulary?*, OptumRx (Aug. 8, 2019), https://optumrx.video.uhc.com/media/What+is+a+formularyF/1_tnrtatvy.
[58] *Id*.

patients, lowering costs for the system, and improving the health care experience for consumers." [59]

90. These statements do not accurately represent the way the PBM Defendants impact drug pricing. As discussed below, the PBM Defendants significantly contribute to, and benefit from, the dysfunctional market dynamic they create—a dynamic that harms consumers.

91. The PBM Defendants' deceptive representations mask their impact on the market, making the black box of drug pricing even more difficult to understand and regulate.

II. The PBM Defendants Drive Up Drug Prices by Leveraging Formulary Decisions to Extract Increasingly Steeper Payments from Manufacturers

92. The PBM industry is heavily concentrated. The PBM Defendants are the three largest PBMs and are owned by large healthcare conglomerates: (1) CVS Caremark (owned by CVS Health which also owns CVS Pharmacy—the largest retail pharmacy chain in the United States); (2) Express Scripts (owned by Cigna); and (3) OptumRx (owned by UnitedHealth Group).

93. Collectively, the PBM Defendants manage 80% of drug benefits for more than 220 million Americans—making preferred placement on their drug formularies a significant bargaining chip when negotiating payments from prescription drug manufacturers.[60] On information and belief, the PBM Defendants similarly dominate the market for drug benefits in Puerto Rico as well.

94. The PBM Defendants began increasingly exerting their leverage in 2012 by excluding drugs from certain therapeutic classes from their formularies to intensify competition

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[59] *Testimony of John M. Prince, Chief Executive Officer, OptumRx, Before the United States Senate Committee on Finance "Drug Pricing in America: A Prescription for Change, Part III"*, at 1 (Apr. 9, 2019), https://www.finance.senate.gov/imo/media/doc/John%20Prince%20OptumRx%20Testimony%20Senate%20Finance%20Committee_04.09.19.pdf

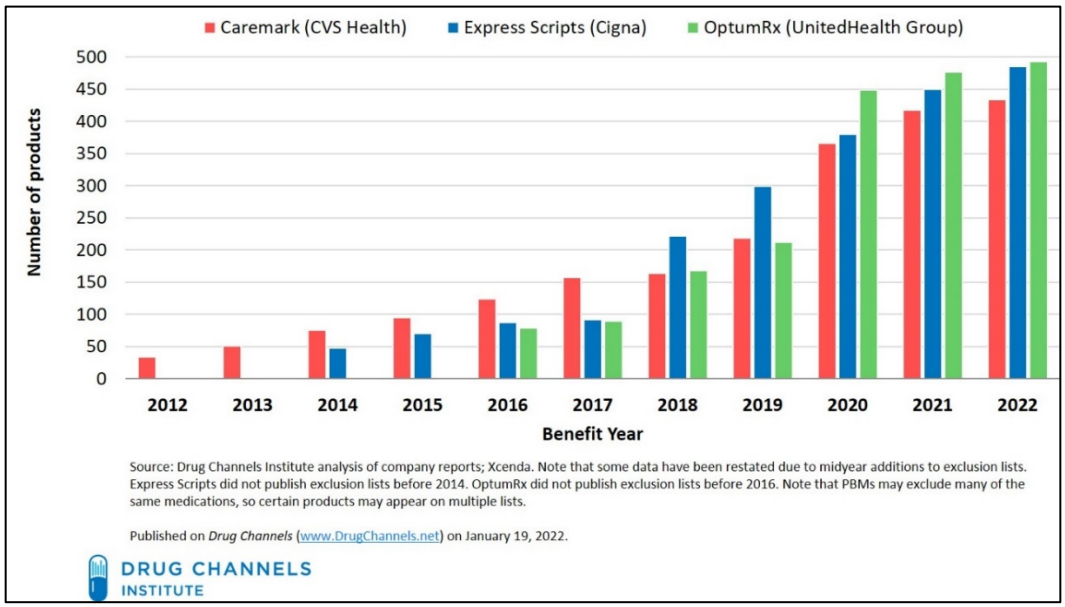
[60] Senate Insulin Report, *supra* note 8 at 68.

among manufacturers for rebates. The threat of exclusion fundamentally changed drug pricing. Rebates went from modest discounts to steep payments that manufacturers were all but forced to make because not paying the PBM Defendants could ruin a drug's chance of success. Over time, rebates have become a significant factor manufacturers consider when setting drug prices.

A. The PBM Defendants Exclude Drugs from Their Formularies to Increase Rebates

95. CVS Caremark started excluding drugs from its formulary in 2012. Express Scripts and OptumRx began the practice in 2014 and 2016, respectively (see graph below showing the number of exclusions by PBM per year).[61] On information and belief, these formulary changes are made on a nationwide basis and affect benefits offered to Puerto Rico residents.

Figure 2: PBM Formulary Exclusions from 2012-2022



96. The number of medicines excluded from the PBM Defendants' formularies increased 961% from 2014 (109 unique drugs exclusions) to 2022 (1,156 unique drug

[61] Adam Fein, *Five Takeaways from the Big Three PBMs' 2022 Formulary Exclusions,* Drug Channels (Jan. 19, 2022), https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html.

exclusions).[62] Drugs used to treat chronic conditions—including insulin, antidepressants, antipsychotics, and antiarrhythmics—are most frequently excluded by the PBM Defendants.

97. On the surface, excluding products from formularies would seem to be a cost control measure, allowing the PBM Defendants to steer prescriptions to a cheaper drug. In practice, it creates an auction for the PBM Defendants to sell their formulary space to the highest bidding drug company. The overall amount prescription drug manufactures paid in rebates and other fees nationally doubled from 2013 ($83 billion) to 2018 ($166 billion).[63] For example, Sanofi increased its rebates from 2-4% in 2013 to 56% in 2018.[64] This would not have happened without the credible threat of exclusion. A Tufts University study found that when PBMs excluded one drug in the same therapeutic class as another drug they did include, the more cost-effective drug was excluded half the time.[65]

98. The PBM Defendants' treatment of biosimilars perfectly illustrates the perverse incentives in drug pricing. A biosimilar is an FDA-approved biologic that is highly similar to, and has no clinically meaningful difference from, another biologic that is already FDA-approved (referred to as the reference product or original biologic).[66] Biosimilars directly compete with

[62] Xcenda, *Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access* at 2 (May 2022), https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[63] Gill, *supra* note 36.
[64] Senate Insulin Report, *supra* note 8 at 67.
[65] Joshua P. Cohen et al., *Rising Drug Costs Drive the Growth of Pharmacy Benefit Managers Exclusion Lists: Are Exclusion Decisions Value-Based?*, 53 (Supp 1) Health Servs. Rsch., 2767, 2764 (Aug. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6056588/pdf/HESR-53-2758.pdf.
[66] U.S. Food and Drug Administration, *Biosimilar and Interchangeable Products*, https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products (last updated Oct. 23, 2017).

existing biologic products but are generally lower priced. Yet, despite being cheaper, two out of every three approved biosimilar product is excluded by one of the PBM Defendants.[67]

99. For example, Viatris (a company formed by the merger between Mylan and Upjohn) launched two identical biosimilar insulins that are fully interchangeable with Sanofi's top-selling Lantus.[68] One product is a branded biosimilar insulin called Semglee. The other product is a generic biosimilar insulin (Insulin Glargine). Semglee has a WAC price 5% below Lantus. Insulin Glargine has a WAC price 65% lower than Lantus. Semglee and Insulin Glargine are the exact same product—the only difference between the two products is price.

100. In their 2022 formularies, none of the PBM Defendants preferred the insulin product with the lowest WAC price (Insulin Glargine).[69] OptumRx preferred Lantus and excluded Semglee but failed to even mention Insulin Glargine. Express Scripts preferred the higher-priced biologic (Semglee) and excluded the lower-priced biologic (Insulin Glargine)—even though Semglee and Insulin Glargine are identical. CVS Caremark excluded Lantus and preferred Basaglar—a product that is not even a biosimilar to Lantus—without mentioning Semglee or Insulin Glargine.[70]

101. Often CVS Caremark's preferred or recommended products are excluded by Express Scripts, and vice versa—further suggesting exclusions are not evidence- or value-based.[71]

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[67] Xcenda, *supra* note 62.
[68] Adam Fein, *Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira*, Drug Channels (Nov. 9, 2021), https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html.
[69] *Id*.
[70] *Id*.
[71] Cohen, *supra* note 65.

B. The PBM Defendants' Rebate Tactics Lead to WAC Price Inflation

102. With respect to both insulin and other prescription drugs, manufacturers compensate for rising rebates and other payments to PBM Defendants by increasing the WAC price to maintain profit margins and to buy space on formularies. Over time, the gap between the WAC price and the net price (the price the manufacturer receives for selling the drug) has become significant.

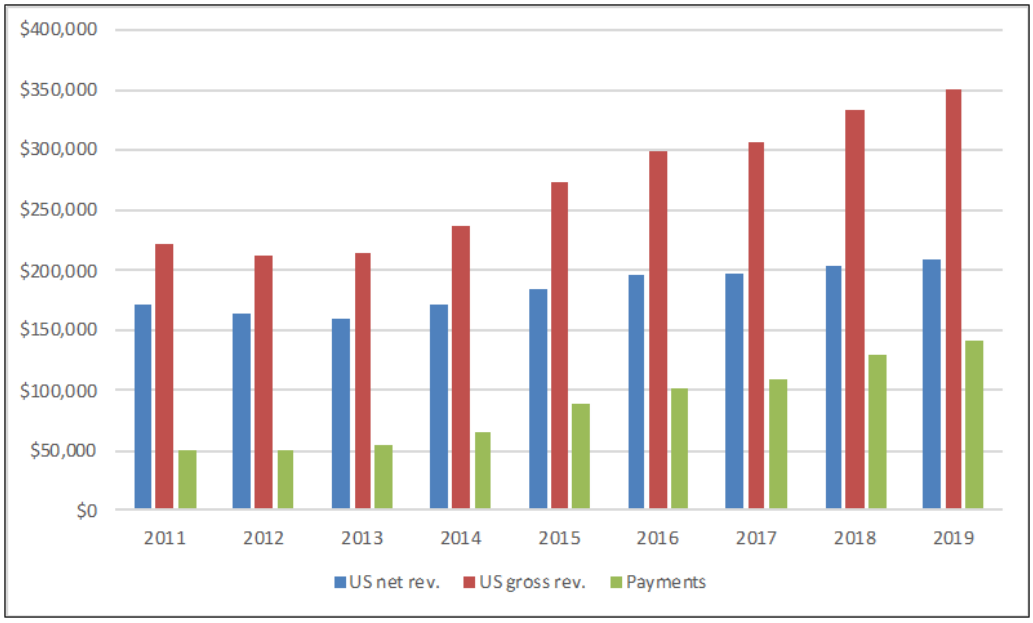
103. From 2011 to 2019, the prescription drug manufacturer payments (mostly rebates to PBMs) nearly tripled.[72] In 2011, manufacturers paid 29.2% of their net revenue ($50.1 billion) to generate $171.8 billion in net sales. By 2019, the same manufacturers paid over twice that amount: 67.4% of net revenue ($141.4 billion) to generate $209.9 billion in net sales.

104. One of the Senate Finance Committee's key findings is that WAC prices for insulin rose sharply between 2013 and 2019 in step with an exponential increase in rebates for these products.[73]

105. Around 2014—when the PBM Defendants' exclusion tactics created a rise in rebates—WAC prices and payments from manufacturers began growing disproportionately higher than manufacturers' net revenue (as shown in the graph below).

[72] Gill, *supra* note 36.
[73] Senate Insulin Report, *supra* note 8 at 7.

Figure 3: Prescription Drug Manufacturer Revenue & Payments from 2011-2019



106. A 2020 study found that for prescription drugs sold from 2016 to 2018, on average, a $1 increase in rebates was associated with a $1.17 increase in the WAC price.[74]

107. The Manufacturing Defendants have artificially inflated list prices for their insulin products to purchase formulary coverage from the PBM Defendants' while maintaining profit margins. For example: [75]

a. Eli Lilly increased the WAC price for its rapid-acting insulin, Humalog 50-50 Kwikpen, from $323 in 2013 to $530 in 2017—an increase of $207 (or 64%) in four years;

b. Novo Nordisk increased the WAC price for its long-acting insulin pens, Levemir FlexTouch, from $303 in May 2014 to approximately $462 in

[74] Neeraj Sood et al, *The Association Between Drug Rebates and List Prices*, USC Schaeffer Center (Feb. 11, 2020), https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/.
[75] Senate Insulin Report, *supra* note 8 at 6.

January 2019—an increase of $159 (or 52%) in a little more than five years; and

c. Sanofi increased the WAC price for its long-acting insulin pens, Lantus Solostar, from $303 in 2014 to $404 in 2019—an increase of $100 (over 33%) in 5 years.

108. Driven by these price hikes, payers' and diabetics' spending on insulin products has skyrocketed with totals in the tens of billions of dollars. Upon information and belief, the PBM Defendants' practices also increase the price and consumers' out-of-pocket costs for non-insulin medications.

III. Defendants Profit from Inflated WAC Prices and High Rebates

109. The market for insulin products is unique in that it is highly concentrated with, until recently, little to no generic/biosimilar options and the drugs have similar efficacy and risk profiles. In fact, the PBM Defendants treat insulin products as commodity products in constructing their formularies. In such a market, where manufacturing costs have significantly decreased, the PBM Defendants should have great leverage in negotiating with manufacturers to drive prices down in exchange for formulary placement. But the PBM Defendants do not want the prices for insulin products to go down because they make more money on higher prices, as do the Manufacturer Defendants. As a result, Defendants have found a way to game the system for their mutual benefit.

110. The PBM Defendants are incentivized to drive up WAC prices. Typically, they retain a portion of the manufacturer payments they negotiate. Thus, the larger the spread between manufacturer payments and WAC prices, the greater the potential for the PBM Defendants to profit.

111. CVS Health (CVS Caremark's parent company) admitted that CVS Caremark profits from the inflated list price/high rebate dynamic in 2019 when CVS Health reported that

CVS Health missed its projected earnings, because CVS Caremark "was experiencing a squeeze related to . . . rebates" and "seeing slower growth than it . . . expected in the list prices of branded drugs."[76]

112. The PBM Defendants claim that the Manufacturing Defendants—not PBMs—are responsible for inflating WAC prices. This is misleading. The Manufacturing Defendants set the WAC price for their drugs; however, the PBM Defendants indirectly control list prices by negotiating drug rebates so high that manufacturers must raise the WAC price to protect both companies' profit margins.

113. Internal documents from Novo Nordisk show that in 2018 the company considered, but ultimately decided against, lowering the WAC prices for its insulin products by 50%. The company's pricing committee warned that reducing the WAC price posed significant financial risk to the company—even though the manufacturer's net price would remain the same. One of Novo Nordisk's primary concerns was facing retributive action from other entities in the pharmaceutical supply chain that derive payments based on the WAC prices (like the PBM Defendants). Novo Nordisk specifically identified as downsides "formulary removal" and "CVS, ESI, & Optum push to be kept whole." In other words, Novo Nordisk worried that if it set the WAC prices for its insulin products at their true cost (Novo Nordisk's net price) instead of an inflated price with a 50% rebate, Novo Nordisk risked being removed from the PBM Defendants' formularies or having to pay the PBM Defendants their cut of the now eliminated 50% rebate.

114. By inflating the WAC prices in response to the PBM Defendants' practices, the Manufacturing Defendants are able to protect their revenues by buying access to formularies, even

[76] Sharon Terlep and Joseph Walker, *Generic-Drug Trends Squeeze Walgreens Profit*, Wall St. J. (Apr. 2, 2019), https://www.wsj.com/articles/walgreens-cuts-earnings-guidance-after-a-challenging-second-quarter-11554204891.

at the expense of margin. The Senate Finance Committee found that as rebates increased, the net prices decreased, though the WAC price for insulin medications doubled in some cases. Sanofi's Lantus's net price was $87.48 in 2016, which was $32 lower than the 2014 net price, but still double the net price of $36.92 in 2005. Eli Lilly's Humalog KwikPen's list price increased from $57 to $106 from 2013 to 2016, while the net price remained relatively constant, going from $26 in 2013 to a high of $28 in 2015 and $24 in 2018[77].

115. As the Senate report further notes, "average net prices for insulin—that is, the revenue manufacturers receive after paying rebates—have declined in recent years due to the growth of rebate sizes. However, manufacturers are still retaining higher average net prices, and, thus, generating *more revenue per unit of insulin* than they were during the first decade of the 21st century."[78] (emphasis added).

IV. Defendants' Manipulation of Drug Pricing Harms Consumers

116. Defendants' tactics to manipulate drug pricing harm Puerto Rico consumers. The most obvious harm is increased prices. These increased prices are not absorbed by other payers, as consumers pay more for any out-of-pocket costs, such as co-pays, deductibles, or uninsured care tied to the WAC price.

117. At an April 2019 Congressional hearing on the rising cost of insulin, Novo Nordisk's President acknowledged that the "perverse incentive" in drug pricing harms consumers:

> [T]here is this perverse incentive and misaligned incentives and this encouragement to keep list prices high, and we've been participating in that system because the higher the list price, the higher the rebate. . . . There's a significant demand for rebates. . . . [W]e're spending almost $18 billion a year in rebates, discounts, and fees, and we have people with insurance with diabetes that don't get the benefit of that.[79]

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[77] Senate Insulin Report, *supra* note 8 at 44-45.
[78] Senate Insulin Report, *supra* note 8 at 89.
[79] *Priced Out Of A Lifesaving Drug: Getting Answers On The Rising Cost Of Insulin Before the Subcomm. On Oversight and Investigations*, 116th Cong. 86, 88 (2020) (Statement of Doug

118. At that same hearing, an executive from Sanofi stated: "I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient."[80]

119. Beyond pricing, drug exclusions present harm by forcing non-medical switching, altering a consumer's drug therapy for reasons other than a drug's efficacy, side effects, or clinical outcome. In other words, the choice of drugs available to consumers becomes driven not by which drug is safest or most effective for consumers, but on financial side-deals governing whether and at what cost-share a drug is placed on a PBM's formulary.

120. Even when diabetics can still afford their diabetic medications, as a direct result of PBM Defendants shifting which insulin products are favored on their formularies ("non-medical switching"), diabetics are often forced to switch medications every few years or go through a lengthy appeal process (or try the favored drug first) before receiving the patient's preferred medication.

121. Non-medical switching for biologic drugs, such as insulin products, causes increased health problems for diabetics and increased healthcare costs for diabetics, payers, and the healthcare system.

122. In 2008, CVS Caremark entered into a $38.5 million settlement agreement with 28 State Attorneys General to resolve allegations that the PBM engaged in deceptive business practices by encouraging doctors to switch consumers to different brand-name drugs by saying the

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Langa, President of Novo Nordisk), https://www.congress.gov/event/116th-congress/house-event/LC65499/text?s=1&r=1.

[80] *Id*. at 112 (Statement of Kathleen Tregoning, Executive Vice President for External Affairs of Sanofi).

consumers or their health plans would save money without disclosing that the drug switching would benefit CVS Caremark.[81]

123. In the intervening years, the basic business practices have not changed, but have only become more profitable to the PBM Defendants, still at consumers' expense. The PBM Defendants have claimed that formulary exclusions only affect a small percentage of consumers. However, each of the PBM Defendants manage prescription drug coverage for tens of millions of consumers. This means that hundreds of thousands of individuals may be forced to switch from their current medication to their PBM's preferred alternative each year. Further, because medications to treat chronic diseases are among the most frequently targeted by formulary exclusions, vulnerable patients with chronic illnesses—like diabetes—are disproportionately affected.[82]

124. For these patients, who often have treatment regimens involving multiple medications that need to work together, having access to their choice of medications can be critical. Frequent changes can be particularly problematic, as changes in one medication can trigger the need for other changes and disrupt treatment.[83]

125. Moreover, because each of the PBM Defendants exclude different medications, and different health plans contract with different PBMs, consumers who change jobs and/or health plans may find their current medications are not covered.[84]

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[81] Illinois Attorney General, *Madigan, 28 Attorneys General Reach Settlement with Caremark for Drug Switching Practices* (Feb. 14, 2008), https://www.illinoisattorneygeneral.gov/pressroom/2008_02/20080214.html.
[82] *Id*. at 11.
[83] *Id*.
[84] *Id*.

CLAIMS FOR RELIEF

COUNT ONE

Violation of the Fair Competition Act 10 L.P.R.A. § 259
Deceptive Acts and Practices

126. The Government re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

127. 10 L.P.R.A. § 259 prohibits unfair methods of competition and unfair or deceptive acts or practices in trade or commerce.

128. At all times relevant to this Complaint, the PBM Defendants engaged in deceptive acts or practices in trade or commerce in violation of 10 L.P.R.A. § 259 by:

a. Misrepresenting that the PBM Defendants function to lower the cost of insulin products;

b. Misrepresenting that rebates and other payments from the Manufacturing Defendants lower the cost of insulin products;

c. Misrepresenting that rebates and other payments from the Manufacturing Defendants do not inflate the WAC price for insulin products;

d. Misrepresenting that formulary decisions are evidence and/or value based;

e. Failing to disclose that the cost share payments insured consumers pay for insulin products are tied to inflated WAC prices rather than the prices that the PBM Defendants and/or third-party payers actually pay for insulin products;

f. Failing to disclose that the PBM Defendants financially benefit from inflated WAC prices which allow them to negotiate substantial rebates and

other payments from the Manufacturing Defendants for insulin products; and

g. Failing to disclose that the PBM Defendants financially benefit from preferring and/or excluding certain insulin products in their formularies.

129. At all times relevant to this Complaint, the Manufacturing Defendants engaged in deceptive acts or practices in trade or commerce in violation of 10 L.P.R.A. § 259 by:

a. Misrepresenting that rebates and other payments from the Manufacturing Defendants lower the cost of insulin products;

b. Misrepresenting that rebates and other payments from the Manufacturing Defendants do not inflate the WAC price for insulin products;

c. Misrepresenting that the WAC price the Manufacturing Defendants advertise for insulin products is an approximate price that the PBM Defendants and/or third-party payers actually pay for the insulin products;

d. Failing to disclose that the WAC price the Manufacturing Defendants advertise for insulin products is not an approximate price that the PBM Defendants and/or third-party payers actually pay for the insulin products;

e. Failing to disclose that the WAC price is substantially higher than the price the PBM Defendants and/or third-party payers actually pay for insulin products;

f. Failing to disclose that the cost share payments insured consumers pay for insulin products are tied to inflated WAC prices rather than the prices that the PBM Defendants and/or third-party payers actually pay for the insulin products; and

g. Failing to disclose that the Manufacturing Defendants purchase preferred placement on the PBM Defendants' formularies by inflating WAC prices and offering substantial rebates and other payments to the PBM Defendants and third-party payers.

130. Upon information and belief, the Government believes Defendants' conduct is ongoing.

131. The Defendants' misrepresentations and omissions were material and likely to mislead consumers and third-party payers.

132. The Defendants' deceptive practices constitute multiple violations of 10 L.P.R.A. § 259.

COUNT TWO

Violation of the Fair Competition Act 10 L.P.R.A. § 259
Unfair Acts and Practices

133. The Government re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

134. 10 L.P.R.A. § 259 prohibits unfair methods of competition and unfair or deceptive acts or practices in trade or commerce.

135. At all times relevant to this Complaint, the Defendants engaged in unfair acts or practices in trade or commerce in violation of 10 L.P.R.A. § 259 by engaging in a scheme to inflate the WAC price for insulin products to allow the PBM Defendants to extract higher fees and the Manufacturer Defendants to secure preferred formulary placement thereby guaranteeing success for their insulin products.

136. Defendants' unfair acts and practices are likely to cause substantial injury to consumers that consumers cannot reasonably avoid. These unfair acts and practices are also not outweighed by any countervailing benefit to consumers or to competition.

137. Upon information and belief, the Government believes Defendants' conduct is ongoing.

COUNT THREE

Violation of the Fair Competition Act 10 L.P.R.A. § 259
Unfair Methods of Competition

138. The Government re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

139. 10 L.P.R.A. § 259 prohibits unfair methods of competition, and unfair or deceptive acts or practices in trade or commerce.

140. Defendants' business practices described herein constitute unfair methods of competition, including Defendants' practice of artificially inflating the WAC price for insulin products to allow the PBM Defendants to extract higher fees and to allow the Manufacturer Defendants to secure preferred formulary placement thereby guaranteeing success for their insulin products.

141. Defendants' practices harm competition because they distort the market for insulin products by inflating the price for insulin products beyond their fair market value and restricting consumers' access to these life-saving medications. In addition, Defendants' practices disadvantage manufacturers unwilling to pay exorbitant rebates and other payments—even if those manufacturers make a superior or more cost-effective insulin product. Defendants' practices also disadvantage PBMs that are not engaging in similar practices because it makes them less

competitive in the PBM market and lessens their abilities to lower drug costs for their clients and ultimately consumers.

142. Upon information and belief, the Government believes Defendants' conduct is ongoing.

COUNT FOUR

Violation of the Fair Competition Act 10 L.P.R.A. 268(b)
Government Damages

143. The Government re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

144. 10 L.P.R.A. § 268 states "Whenever the Commonwealth of Puerto Rico . . . shall suffer damages caused by any person by reason of acts or intended acts forbidden or declared unlawful by the provisions of this chapter, it may sue therefor for the recovery of damages[.]"

145. Defendants are "persons" under 10 L.P.R.A. § 257 because they are corporations.

146. As described above, Defendants' unfair and deceptive scheme to inflate the WAC price for insulin products allowed the PBM Defendants to extract higher fees and the Manufacturer Defendants to secure preferred formulary placement thereby guaranteeing success for their insulin products. This scheme ultimately resulted in artificially inflated prices across the market for Manufacturer Defendants' products because the Manufacturers WAC price remains constant regardless of who is purchasing that product.

147. The Government did not contract directly with the PBM Defendants in this action. However, it was still forced to pay inflated WAC prices for insulin and other drugs because the PBM Defendants and Manufacturer Defendants' illegal scheme resulted in the higher WAC price for those drugs.

148. Defendants' unlawful conduct thus damaged the Government by increasing the price the Government paid for insulin products.

149. The Government is not seeking relief relating to any federal program (*e.g.*, Medicaid, Medicare) or any contract related to a federal program. Moreover, the Government's claims do not arise out of a written contract, but rather are based on the larger unfair and deceptive scheme that violates the Fair Competition Act.

150. Upon information and belief, the Government believes Defendants' conduct is ongoing.

PRAYER FOR RELIEF

The Government of Puerto Rico prays for entry of judgment against Defendants individually, and jointly and severally, for all the relief requested herein and to which the Government may otherwise be entitled, including, without limitation:

A. The Court enter an Order and Judgment against Defendants and in favor of the Government for each violation alleged in this Complaint;

B. Declare that Defendants' acts and practices alleged herein are unfair and deceptive practices and/or constitute unfair methods of competition in violation of 10 L.P.R.A. § 259; and that Defendants' conduct breached and violated the statutory causes of action alleged herein;

C. Enjoin Defendants from engaging in unfair and deceptive practices and unfair methods of competition in violation of 10 L.P.R.A. § 259.

D. Require Defendants to pay all consumer restitution that may be owed to Puerto Rico consumers affected by Defendants' unlawful acts and practices;

E. Require Defendants to disgorge ill-gotten gains;

F. Require Defendants to pay for the damages incurred by the Government as a result of Defendants' unfair and deceptive scheme resulting in increased insulin prices pursuant to 10 L.P.R.A. § 268(b).

G. Given the repeated and ongoing violations of the law, punish violations of 10 L.P.R.A. § 259 by an Order requiring Defendants to pay maximum civil penalties under 10 L.P.R.A. § 269 for each and every violation of section 259;

H. Assess and award a judgment in favor of the Government and against Defendants for attorneys' fees and costs and pre- and post-judgment interest; and

I. Award any and all other relief this Court deems appropriate.

RESPECTFULLY SUBMITTED.

In San Juan, Puerto Rico, this 24th day of January, 2023.

DOMINGO EMANUELLI
SECRETARY OF JUSTICE
DEPARTMENT OF JUSTICE
OF PUERTO RICO

/s/ *Guarionex Díaz Martínez*
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